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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,138	09/10/2001	Atsushi Sugiyama	534037MO	9406

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EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/03/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/926,138

Applicant(s)

Sugiyama

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 1, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above, claim(s) 11-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Mar 13, 2000 is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4, 5 6) ☐ Other:

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DETAILED ACTION

Claims 1-22 are pending. Claims 1-9 are considered on the merits. Claims 10-22 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claims 10-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected inventions, the requirement having been traversed in Paper No. 7.

The traversal is on the ground that the groups should require the same area of search and thus the groups do not have independent classification. This is not found persuasive because the application is a 371 of a PCT and under PCT Rule 13.1 and 13.2 and 35 USC 121, 372 classification is not an element included in the determination of independent inventions.

However, Groups I and II have been rejoined for examination.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 7 and 8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5,618,665 [A].

The claims are directed to a method of determining cAMP content or adenylate cyclase activity in a sample comprising:
adding apyrase, alkaline phosphatase and adenosine deaminase to the sample,
enzymatically converting cAMP to AMP,
assaying AMP without using radioactive agents.

The references are relied upon as explained below.

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US 5,618,665 discloses in example 10, a method of determining cAMP concentration in a biological sample comprising:
adding apyrase, alkaline phosphatase and adenosine deaminase to the sample (col. 22, ls. 52-55),
determining cAMP concentration fluorometrically (col. 23, l. 64) using phosphodiesterase (col. 22, l. 65), using glycogen phosphorylase and P_i (col. 4, l. 21-24), using phosphoglucomutase, G-6-P dehydrogenase (Table 1, reactions 2.b.c. (col. 4, ls. 25-29).

Claims 1, 2, 4-6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sawada *et al.* [AS1].

The claims have been discussed above.

Sawada *et al.* disclose the instant method, see Fig. 1, and Part B on page 92. All reagents used in the instant method are used in the method of Sawada *et al.*.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,618,665 [A].

The claims are directed to a method of determining cAMP content or adenylate cyclase activity in a sample comprising:
adding apyrase, alkaline phosphatase and adenosine deaminase, glucose

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oxidase and glycogen phosphorylase to the sample, enzymatically converting cAMP to AMP, assaying AMP without using radioactive agents.

The references are relied upon as explained below.

US 5,618,665 discloses in example 10, a method of determining cAMP concentration in a biological sample comprising: adding apyrase, alkaline phosphatase and adenosine deaminase to the sample (col. 22, ls. 52-55), and optionally adding glucose oxidase or glycogen phosphorylase to remove exogenous glycogen, (Table 1, reactions 1.B, a.c., lines 15-25, col. 4, l. 10-20) determining cAMP concentration fluorometrically (col. 23, l. 64).

The use of both glucose oxidase and glycogen phosphorylase in the cleaning reaction system of '665 would have been obvious since '665 teaches that either of these may be used in the cleaning reaction phase of the reaction. Since the reason to include each of these enzymes individually is to remove glycogen as an interfering substance, one of skill in the art may add both together to obtain the same result in the absence of evidence to the contrary.

The heating of the reaction mixture and adding NADP⁺ to increase the concentration of NADPH would have been obvious because '665 teaches this step as an option (col. 4, l. 52-59).

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,618,665 [A] as applied to claims 1-4, 7-9 above, and further in view of Sawada *et al.* [AS1] and Omburo *et al.* [U].

The claims are further directed to the addition of a chelator to inactive phosphodiesterase.

US 5,618,665 terminates the phosphodiesterase reaction by addition of base (col. 18, ls. 21-25) or by heating (col. 23, l. 6).

Omburo *et al.* teach that cAMP-phosphodiesterase (cGMP-inhibited phosphodiesterase) is inhibited by chelators such as EDTA (abstract).

Sawada *et al.* neither heats nor adds base to the mixture after the reaction

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with phosphodiesterase, but rather adds EDTA after completion of the phosphodiesterase catalysis of cAMP to AMP and production of F-6-P (page 92, Part B). While Sawada *et al.* do not explain why the EDTA is added to the reaction mixture, the result would inherently be the inactivation of cAMP-phosphodiesterase which is known to be inhibited by chelators such as EDTA because cAMP-phosphodiesterase is a metalloenzyme as discussed by Omburo *et al.* Therefore, it would have been obvious to substitute the addition of EDTA to the reaction mixture for the heating or base addition taught in '665 when taken with Sawada *et al.* who adds EDTA to the reaction mixture and Omburo *et al.* who discloses that cAMP-phosphodiesterase is inhibited by chelators such as EDTA.

One of ordinary skill in the art would have been motivated at the time of invention to perform these reactions and make these substitutions in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier
Primary Examiner
Art Unit 1651
May 22, 2003